

### **REMARKS**

This case has been reviewed and analyzed in view of the Official Action dated 18 December 2003. Responsive to the objections and rejections made by Examiner in the Official Actions, Claims 10-12 have been amended to more clearly clarify the inventive concept of the Applicant.

The Examiner has objected to the Specification due to the inclusion of Chinese characters on Page 2 of the Specification as originally filed. The Specification, however, has now been amended and the proper English name has been inserted therein. No new subject matter has been inserted therein because the amendment is merely a translation of the name written in Chinese.

Additionally, the Specification has been amended to change "glucose" in the Paragraph on Page 17, Lines 9-16 to "glucosyl". It is not believed that this constitutes the insertion of new matter, because this is merely the correction of a typographical error.

The Examiner has further rejected Claims 10-12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Claims 10, 11, and 12, however, have now been amended and it is believed that newly-amended Claims 10-12 now satisfy the requirements of 35 U.S.C. § 112, second paragraph.

It is believed that prior to a discussion of the Examiner's further objections and rejections made in the outstanding Official Action, it may be beneficial to briefly review

the subject Patent Application system in light of the inventive concept of the Applicant. The subject Patent Application system is directed to the preparation and compositions of *Antrodia Camphorata* mycelium biologically active material. A biologically active material derived from *Antrodia Camphorata* mycelium is obtained through the liquid culturing of the *Antrodia Camphorata* mycelium. The biologically active material contains significant amounts of polysaccharides therein with the polysaccharides comprising  $\beta$ -1,3-D-furan dextran with a  $\beta$ -(1-6)-glucosyl branched chain. The polysaccharides have a molecular weight in the range of 500,000 to 2,000,200.

The Examiner has rejected Claims 10-12 under 35 U.S.C. § 102(e) as being anticipated by the Li reference or the Huang reference in light of Hseu, and Wu. It is the Examiner's contention that each of the Li and Huang references discloses biologically active material obtained from *A. Camphorata* which inherently contain the required derived compositions comprising polysaccharides either derived as a part of the mycelium compositions or derived as part of the culture medium material containing substances, such as polysaccharides secreted into the culture medium.

The Li Patent #6,558,943 is directed to a method for propagating fungi using solid state fermentation. In Example 4 of the Li reference, various fungi, which include *Ganoderma Lucidum*, *Antrodia Camphorata*, *Trametes Versicolor*, and *Agaricus Blazei*, which were cultivated using solid state fermentation. The Li reference is directed to using a solid state fermentation method for the propagation of the fungi.

The method and system of the subject Patent Application, however, derive a biologically active material from *Antrodia Camphorata* mycelium utilizing the liquid culturing of the *Antrodia Camphorata* mycelium. The liquid culturing technique lends itself to the production of biologically active material containing significant amounts of polysaccharides.

Additionally, the Li reference only analyzes the polysaccharide content of the *Agaricus Blazei*, and does not mention the polysaccharide content of the *Antrodia Camphorata*. Further, the polysaccharides are not specifically identified and it is not taught or even suggested that the polysaccharides would comprise the  $\beta$ -1,3-D-furan dextran with a  $\beta$ -(1-6)-glucosyl branched chain.

The Huang Patent #6,355,475 is directed to an isolate of *Antrodia Camphorata*, a process for producing a culture of the same, and a product obtained thereby. As described in Example 3 of the Huang reference, the culture filtrates of *A. Camphorata* collected as experimental examples (see Examples 1 and 2) and the inoculated media, or control samples, were used for MTT assay. These culture filtrates are used to directly kill tumor cell lines.

In the composition and method of the subject Patent Application, it is the fermentation, freezing, and then drying of the *A. Camphorata* mycelium, as described in Examples 5B and 6 of the subject Patent Application, which are used on live animals. In the Huang reference, it is the entire culture filtrate of *A. Camphorata* which is used to

directly kill the tumor cell lines. In the system of the subject Patent Application, however, it is the mycelium, as opposed to the entire culture filtrate, which is used to experiment on live animals, which is significantly different from the direct killing of the tumor cell lines.

The Examiner has cited the Hseu reference merely to show evidence of high polysaccharide contents found in the *Ganoderma* species; and the Examiner has further cited the Wu reference merely to demonstrate that *A. Camphorata* is conspecific with *Ganoderma Camphoratum*. Neither of these references describes a biologically active material obtained from the liquid culturing of *Antrodia Camphorata* mycelium, and neither show the particular polysaccharides derived in the subject Patent Application system and method.

Therefore, neither the Li reference, nor the Huang reference, taken in light of the Hseu reference or the Wu reference, provide for: "...biologically active material being obtained from liquid culturing of *Antrodia Camphorata* mycelium, said biologically active material containing significant amounts of polysaccharides therein, said polysaccharides comprising  $\beta$ -1,3-D-furan dextran with a  $\beta$ -(1-6)-glucosyl branched chain, said polysaccharides having a molecular weight in the range of 500,000 to 2,000,200...", as is clearly provided by newly-amended Independent Claim 10.

Thus, based upon the newly-amended Independent Claim 10, it is not believed that the subject Patent Application is anticipated by, or made obvious by, either the Li

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reference, or the Huang reference, when taken alone or in combination, and further in light of the Hseu reference or the Wu reference, when Independent Claim 10 is carefully reviewed.

It is now believed that the remaining Claims 11 and 12 show patentable distinction over the prior art cited by the Examiner for at least the same reasons as those previously discussed for Independent Claim 10.

It is now believed that the subject Patent Application has been placed in condition for allowance, and such action is respectfully requested.

Respectfully submitted,



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